

January 24, 2002

Mr. Paul Helliker  
Director  
Department of Pesticide Regulation  
P.O. Box 4015  
Sacramento, CA 95812-4015

RE: Proposal for Refinement of 1,3-Dichloropropene Use in California Townships

### ***Introduction***

Township caps were established to manage lifetime exposure and risk to 1,3-dichloropropene (1,3-D) in California. Effective 1/1/95, following 5 years of research conducted by Cal-EPA and Dow AgroSciences, no more than ~90,500 pounds of 1,3-D has been permitted for use in any township in California per year. It has been calculated by Cal-DPR that limiting product use density to this annual township limit results in lifetime exposures and risk that are acceptable.

While these general limits were not a significant issue for growers in the six years following 1,3-D reintroduction, current needs in several areas suggest alternative strategies and new types of flexibility in use be investigated and implemented as appropriate. This proposal provides for a transitional plan for 2002 and successive years, beginning with retaining the existing township cap, while increasing the available pounds of 1,3-D per year on a township basis by two fold for an interim period.

The opportunity for immediate, short-term relief for the growers of California comes from the fact that in the Cal-DPR risk assessment, lifetime risk (therefore the basis for managing cancer risk potential) is considered a 70 year period. Therefore, to successfully manage lifetime cancer risk to an acceptable level, the **70 YEAR ANNUAL AVERAGE** product use density cannot exceed the limit of ~90,500 pounds of 1,3-D. The amount of 1,3-D use/township/per year is not important - rather, it is the resulting long-term average air concentrations which determines risk. The annual limits (as opposed to 5 or 10 year limits) for township caps is a matter of administrative convenience rather than of regulatory necessity.

DAS proposes averaging of potential exposures for periods greater than one year. That is, allow township uses of 1,3-D in a specific year to exceed the annual stated limit, if in previous or subsequent years, uses would be limited to a corresponding amount below the cap level. This would provide additional inter-year 1,3-D product use flexibility to the California grower community while continuing to manage lifetime (chronic) exposures to 1,3-D at acceptable levels.

The proposed process would adjust all township limits to 2X the existing cap for 2002 and successive years, dependent on use history from 1995 to present. Subsequent refinement would be made based on site specific refinement developed and agreed upon by DAS and DPR. As is available through the current process, use tracking would provide the basis for modified township limits based on retrospective analysis of actual use data

### ***Exposure Assessment***

Recent environmental modeling results (Cryer and van Wesenbeeck, 2000a, 2000b) were evaluated for variability in annual average air concentrations for a hypothetical township that received the annual limit of ~9,500 gallons of 1,3-D. In addition, the modeled scenario assumed all of the adjacent townships (8 adjacent townships – to create a 3 x 3 township grid) in the modeled scenario also received their annual limit of 1,3-D use. The fields treated within the 9 evaluated townships were rotated consistent with “tree and vine” agricultural practices. Actual long-term weather files from Fresno County were used, in combination with the ISCST3 air dispersion model to calculate the range of air concentrations that would be present at each receptor within the township of interest. The 100<sup>th</sup> percentile annual average air concentration was 7.9 µg/m<sup>3</sup>, respectively, across the township during the 20-year simulation period.

A conservative appraisal of exposure would be a proportional doubling effect if the product use within the 9-township grid increased by a factor of 2x over the township analysis based upon the current cap. From a mass balance standpoint, increasing the township cap can occur by several mechanisms. Although not a possibility, the first way to increase mass usage is to double the application rate made to existing treated fields. This would result in predicted township-wide concentration increases of exactly 2x. Second, more fields within the township can be treated at the normal (labeled) rate. Thus, the highest concentrations will occur near treated fields having a 2x rate (scenario 1). The only way the latter scenario will approach the scenario 1 100-percentile value would be if a receptor was located uniformly between the 2 side-by-side fields that happened to be treated on the same day. This is not considered to be a highly probable scenario. Thus, a 2X increase in air concentrations (subchronic, chronic) above that predicted by the simulations results of Cryer and van Wesenbeeck is a conservative approximation for air concentrations if more treated fields (at the normal application rate) were included in the township analysis.

Therefore, within a year that experiences a 2X township cap use level, the annual average air concentrations are not expected to exceed 16 µg/m<sup>3</sup> respectively (i.e, 2x increase of the highest 100-percentile air concentrations). It is important to point out that there is nothing within the proposal that will affect or alter long-term or chronic air concentrations or exposure scenarios. If a township uses 2X the township cap in a single year, there will be another year or series of years, that will limit the use of 1,3-D to less

than the township cap level to establish a long-term average that does not exceed the product use that would have occurred under the existing annual 1,3-D township caps.

### ***Toxicology***

The basis for establishing an acceptable lifetime exposure to a compound is based upon dose or exposure concentration and time of exposure. This is true for nonneoplastic as well as neoplastic endpoints. The latter has been codified in the EPA Office of Research and Development Proposed Guidelines for Carcinogen Risk Assessment (EPA, 1996). For carcinogens, the Guidelines state that a “cumulative dose received over a lifetime, expressed as lifetime average daily dose, is generally considered an appropriate default measure of exposure to a carcinogen” and that “The assumption is made that a high dose of a carcinogen received over a short period of time is equivalent to a corresponding low dose spread over a lifetime”.

The basis for the association of dose level and dosing period (Time) is called Haber’s Law that has been most recently reviewed by Witischi (1999). An early evaluation of the concept of “Dose x Time” relative to carcinogenesis in laboratory animals by Druckry and Kuepfmueller (1948) was discussed. This study examined the concept of Dose x Time experimentally by administering rats with the genotoxic carcinogen butter yellow (dimethylaminoazobenzene). They found that induction of tumors depended on total dose received and not on dose level or time of exposure independently (i.e., the product of the two variables). To produce tumors in the lifespan of the rats required a certain total dosage whether it was acquired in a short time period or a longer time period. A more recent example of a toxicant which has been demonstrated to follow Haber’s Law is the toxicity of a dioxin analogue, hepatachlordibenzo-p-dioxine (Rozman, 1999).

### ***Proposal Example***

With very few exceptions from the period of 1995 to present, use records indicate the majority of CA townships have not reached the 1,3-D township limit. In each township where the cap has historically not been met, starting with 2001, a corresponding amount of 1,3-D can be used beyond the township cap and still maintain 1,3-D use in California within the Cal-DPR regulatory framework that was established in 1995.

As an example, uses in Township X were:

	<u>Actual Used</u>	<u>Township Cap Limit</u>
1995	2,000 gallons	Cap = 9,500 gallons
1996	3,000 gallons	Cap = 9,500 gallons
1997	3,000 gallons	Cap = 9,500 gallons
1998	3,000 gallons	Cap = 9,500 gallons
1999	3,000 gallons	Cap = 9,500 gallons
2000	4,000 gallons	Cap = 9,500 gallons

Total 18,000 gallons  
Township Cap Totals 57,000 gallons

Township X has a credit of 39,000 gallons (57,000 gal - 18,000 gal) available to use in excess of the currently permitted annual limit of 9,500 gallons. In this example, Township X would have an adjusted Township cap of 22,500 gallons/year (39,000/3 years + 9,500 gallons/year) for the next three years. Exposure under these scenario results in lifetime cancer risk that falls within the scientific and regulatory framework that Cal-DPR has approved. No 1,3-D product use in the state occurred during the period from 4/13/90 - 12/7/94. Lack of product use over this time frame adds conservatism to any calculation of lifetime cancer risks for the residents of California.

### ***Risk Characterization and Implications***

As an example, under a proposed use conditions with yearly variable township caps, a 2X increase over the current township cap levels are not expected to exceed  $16 \mu\text{g}/\text{m}^3$  1,3-D air concentrations on a chronic exposure basis. The highest calculated air concentration (100<sup>th</sup> percentile) produce margins of exposure (MOE or safety factors) of 239X when compared to the Cal-DPR chronic NOELs.

Even when using the 100<sup>th</sup> percentile value that would occur within a township during a 20-year period, the calculated MOEs exceed the standard of acceptability of 100X. These calculations indicate that the air concentrations and resulting exposure potentials associated with the proposed retrospective averaging of township caps will not increase the hypothetical risk associated with the use of 1,3-D in California.

### ***Additional Township Limit Refinement***

Tracking data of actual use will allow accurate, retrospective simulations of air concentration distributions and hypothetical risk. These analyses on a township by township basis would incorporate area specific data, evaluating the impact of 2X limits or incrementally higher use scenarios that are deemed appropriate by Cal-DPR. These evaluations would form the basis for subsequent township limit refinement as appropriate.

### ***Implementation***

Many components of implementation for this proposal will be the same as current practices. Since 1998, DAS has utilized a real-time tracking and township cap implementation system through CDMS. Under this system, only DAS certified PCA's are authorized to write recommendations for 1,3-D use. Once the authorized PCA writes a recommendation, the following steps occur:

- 1) The recommendation is electronically submitted to CDMS for approval.

- 2) CDMS electronically checks the recommendation for correctness against the product label and DPR Permit Conditions.
- 3) CDMS validates adjusted pounds of 1,3-D requested, taking into consideration all application factors described by permit.
- 4) The request is checked for available pounds within the township allotment.
- 5) If the amount requested is available, the recommendation is accepted and an NOI (Notice of Intent) can be filed.
- 6) If there is not enough 1,3-D available, a note is displayed, identifying available pounds of 1,3-D and allowing a modified request for available material.

The proposed Transition Plan for 2002:

- 1) Adjust initially available pounds of 1,3-D per township to two times the current cap (181,000 pounds). This allocation of pounds of 1,3-D above the existing cap will continue until unused pounds relative to the cap from 1995 forward are no longer available.
- 2) When use in any township exceeds the current cap, both DPR and the County Ag Commissioner will receive an informal notification.
- 3) For any township that reaches 1.5X the cap, CDMS records will be compared to county records as a Quality Assurance step.
- 4) For townships exceeding the existing limit, DAS will provide a spreadsheet analysis of the township involved, along with each surrounding township. This analysis will compile available 1,3-D use data from 1995 through the 2002 use period. These data will allow site specific analysis for additional use decisions.
- 5) Any additional refinement of available 1,3-D from site specific analysis will be incorporated into this system based on approval of DPR.

### ***Summary***

This proposal to use a limited, retrospective averaging approach to modify annual township limits while retaining the existing township cap. This approach provides for a transitional year of 2002 with available pounds of 1,3-D doubled on an annual basis. The 1,3-D use allowed in the transitional period is consistent with the regulatory framework originally used by DPR for product reintroduction. Additional opportunities for site specific refinement can be explored to augment this proposal pending DPR approval. Existing processes will be modified to accommodate implementation of proposal. Implementation will begin immediately upon receipt of approval from DPR.

Sincerely,

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